

REMARKS

Status of Claims:

Claims 38-39, 42, 44-51, 56-63, 67-70, 72-75, 78-80, 83-84, 86-92, 94-100, 102-105, 107-108, 110-116, 118-119, 121-123, and 126-141 are pending in the application. Each of the pending claims defines an invention that is novel and unobvious over the cited art. Favorable re-consideration and allowance of the present application based on the above-described amendments and the following remarks are respectfully requested.

The applicant does not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserves the right to pursue such subject matter in continuing and/or divisional applications.

Rejection Under 35 U.S.C. § 102(b):

Claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich *et al.* (Hum Reprod. 1994). The examiner alleges that Diedrich *et al.* describe a method for obtaining the production of a fertilizable oocyte within a program of COS/ART comprising (a) administering HMG to induce follicle growth, and (b) administering cetorelix in a dosage regimen of multiple daily doses of 3 mg/day to prevent a premature LH surge, wherein the first daily dose of cetorelix was administered on day 7 of the cycle, and daily treatment continued until ovulation was induced by administration of HCG.

The applicants respectfully submit that the claims of the present application are directed to a method that is different from and is not anticipated by the method described by Diedrich *et al.*

To anticipate a claim, a reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Citations omitted; *see* Manual for Patent Examining Procedure (M.P.E.P.), §2131.

The evidentiary record fails to teach each element of the present invention because Diedrich differently recites a dosing regime for the LHRH antagonist and Diedrich does not maintain the level of endogenous FSH secretion.

The present amendment is presented to clarify the wording of the independent claims with respect to the administration of the LHRH antagonist. In the method of the present invention, a single dose of an LHRH antagonist is administered, or optionally, a second dose may be administered. In contrast, Diedrich teaches daily doses of an LHRH antagonist starting at day 7 and continuing until day 14.

A second distinction over Diedrich relates to suppression of endogenous FSH secretion. The present claims recite “wherein said amount of LHRH antagonist does not suppress endogenous FSH secretion.” Diedrich does not disclose a method whereby the levels of FSH secretion are not suppressed. Diedrich claims they “cannot reach a conclusion regarding FSH suppression.” However, to the extent Diedrich data may speak to this question, Diedrich notes that a decrease in FSH was observed in the luteal phase. (Diedrich, p. 790, col. 1, 3rd paragraph).

Because Diedrich fails to teach at least two elements of the present invention, Diedrich fails to anticipate the present invention under 35 U.S.C. § 102. In view thereof, the applicants respectfully request the examiner withdraw the instant rejection.

Claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 are rejected under 35 U.S.C. 102(a) as being anticipated by Olivennes *et al.*, “Scheduled administration of a gonadotrophin-releasing hormone antagonist (Cetrorelix) on day 8 of in-vitro fertilization cycles: a pilot study,” Human Reprod., 10:1382-86 (1995).

Inventors Bouchard and Frydman are co-authors of the Olivennes publication. The reference publication is related to the research project that gave rise to the present invention. The Olivennes publication is disqualified as a reference because it is a publication of the inventors own work. (See, MPEP § 715.01(c) and § 706.01(c) I, citing In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982)).

In view of the foregoing, withdrawal of the rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35 U.S.C. §102(a) as allegedly being anticipated by Olivennes *et al.* is respectfully requested.

Obvious-Type Double Patenting Rejection

Claims 38-39, 42, 45-51, 56-62, 65, 67-74, 78-82, 86-92, 94-100, 102-105, 107-108, 110-116, 118-119, 121-123, 126-128 and 129-141 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 26-42 of co-pending U.S. Patent Application No. 10/661,780. The claims of Application No. 10/661,780 are directed to a method of treating infertility disorders that comprises inducing follicle growth by administration of hMG or recombinant FSH in combination with clomiphene, which method is considered to be encompassed by the claims of the present application.

The applicants acknowledge that the examiner has maintained the rejection and request the present rejection be held in abeyance until allowable subject matter is indicated.

CONCLUSION

Accordingly, it is respectfully requested that the foregoing amendments be entered, that the application as so amended receive an examination on the merits, and that the claims as now presented receive an early allowance.

In the event the examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

The Commissioner is hereby authorized to charge any fees or credit any overpayment associated with this communication, including any extension fees or fees for the net addition of claims, to Deposit Account No. 033975, Order No. 098501-0235299.

Respectfully submitted,

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